



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

11C

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,209	11/28/2001	William D. Huse	P-IX 5066	3759
23601	7590	11/03/2004	EXAMINER	
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			WESSENDORF, TERESA D	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/997,209	<b>Applicant(s)</b> HUSE, WILLIAM D.	
	<b>Examiner</b> T. D. Wessendorf	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2004 and 18 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 and 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 14-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

***Response to Arguments***

Applicant traverses the restriction of newly added claims 41-43 in that these added claims are encompassed within the claim 1. Claims 41 and 42 is argued to include all the elements of claim 1.

In reply, these newly added claims are drawn to a method of generating the cell composition of claim 1. Claim 1 is a composition claim and not a method. Thus, while the composition of claim 1 is included in the method however, the method contains process steps not found in claim 1.

***Status of Claims***

Claims 1-43 are pending.

Claims 11-13 and 25-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claims 1-10 and 14-24 are under examination.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1639

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-6, 8, 10, 14-17, 20 and 22-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Choi et al (Nucleic Acids Research) for reasons set forth in the last Office action.

#### ***Response to Arguments***

Applicant argues that Choi appears to describe a BAC vector and expression of a BAC library but does not teach the claimed composition.

In reply, attention is directed to page iii wherein Choi describes a composition comprising of a plant cell (i.e., a non-yeast cell, as claimed) transfected with the vector containing the BAC library, as stated by applicants above. See further e.g., Fig. 1 and page vii. Also, the abstract which clearly discloses ".....an alternative approach to random integration of large DNA fragments into plants is to utilize one of several site-specific recombination (SSR) systems, such as Cre lox...." Accordingly, the specific cell composition of Choi fully meets all the claimed limitation of the broad cell composition.

Claims 1-10 and 14-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Zarling et al (U.S. 20030105039) for reasons advanced in the last Office action.

***Response to Arguments***

Applicant submits that Zarling fails to describe a composition transfected with a diverse population of about 10 or more variant nucleic acids. Zarling is argued to describe mutagenesis of an endogenous sequence.

In response, the disclosure of Zarling at [0130]-[0132] of the mismatches being 40% reads on the broad claimed "or more" variants. At [0130] Zarling discloses that the plurality of pairs preferably comprise a pool or library of mismatches. The size of the library will depend on the number of residues to be mutagenized, as will be appreciated by those in the art. Generally, a library in this instance preferably comprises at least 40% different mismatches, with at least 30% mismatches being preferred and at least 10% being particularly preferred. That is, the plurality of pairs comprise a pool of random and preferably degenerate mismatches over some regions or all of the entire targeting sequence. A pool of degenerate variant targeting polynucleotides covering some, or preferably all, possible mismatches over some region are generated, using techniques well

known in the art. At [0131] Zarling discloses that as will be appreciated by those in the art, the introduction of a pool of variant targeting polynucleotides (in combination with recombinase) to a target sequence, either in vitro to an extrachromosomal sequence or in vivo to a chromosomal or extrachromosomal sequence, can result in a large number of homologous recombination reactions occurring over time. That is, any number of homologous recombination reactions can occur on a single target sequence, to generate a wide variety of single and multiple mismatches within a single target sequence, and a library of such variant target sequences, most of which will contain mismatches and be different from other members of the library. This thus works to generate a library of mismatches. See further [0009]-[0012] as to the to this known composition as described in the different prior art and incorporated by reference thereto.

Applicant's argument as to the method of Zarling describing mutagenesis of an endogenous sequence is irrelevant since the composition is known or the same as taught by Zarling.

The rejection of the claims over Stemmer under 102 and 103 no longer applies in view of applicant's arguments.

**Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 11-13, 25-43 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

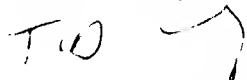
Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D.

Art Unit: 1639

Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw  
October 29, 2004